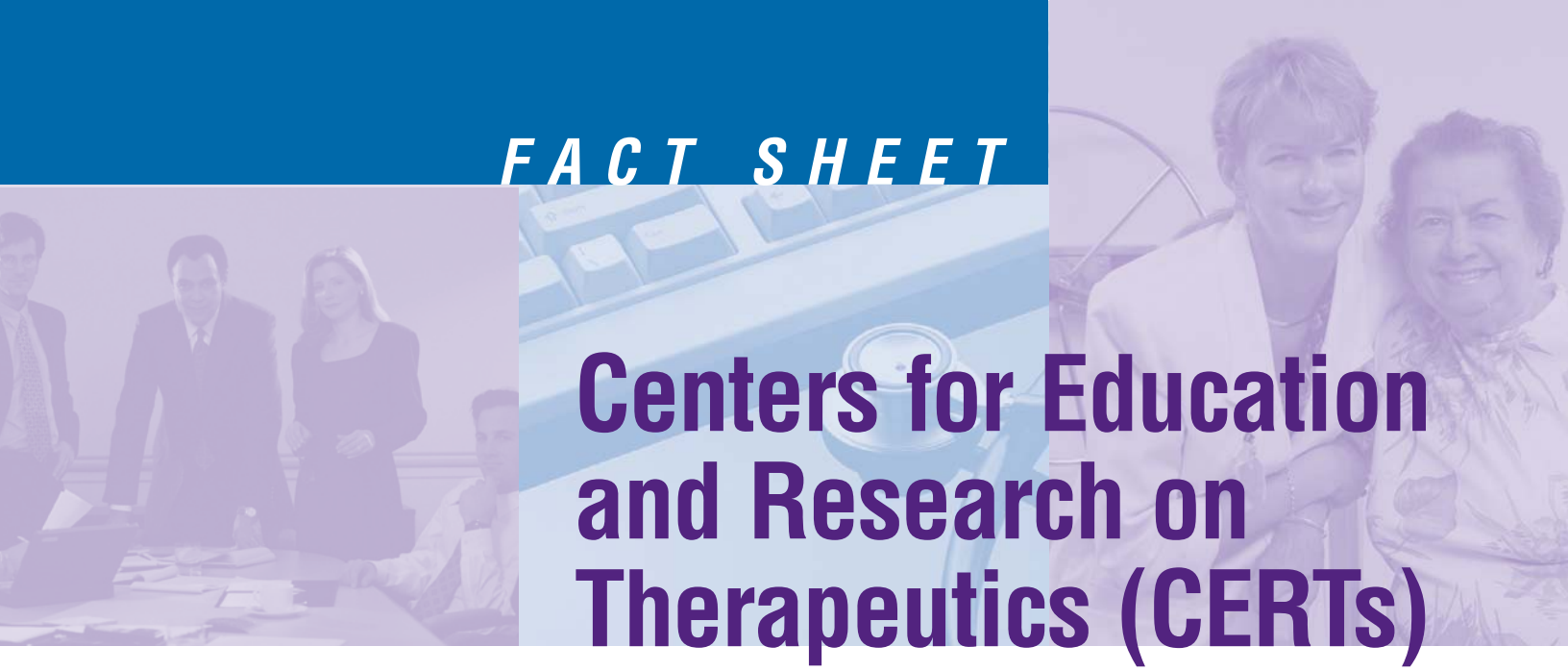
FACT SHEET



Centers for Education and Research on Therapeutics (CERTs)

Agency for Healthcare Research and Quality • 2101 East Jefferson Street • Rockville, MD 20852

www.ahrq.gov

AHRQ is the lead Federal agency charged with supporting research designed to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.

U.S. Department of Health and Human Services
Public Health Service

Purpose

The Centers for Education and Research on Therapeutics (CERTs) demonstration program is a national initiative to conduct research and provide education that advances the optimal use of therapeutics (i.e., drugs, medical devices, and biological products). The program, which consists of seven centers and a Coordinating Center, is administered as a cooperative agreement by the Agency for Healthcare Research and Quality (AHRQ), in consultation with the U.S. Food and Drug Administration (FDA).

The research conducted by the CERTs program has three major aims:

1. *To increase awareness* of both the uses and risks of new drugs and drug combinations, biological products, and devices as well as of mechanisms to improve their safe and effective use.
2. *To provide clinical information* to patients and consumers; health care providers; pharmacists, pharmacy benefit managers, and purchasers; health maintenance organizations (HMOs) and health care delivery systems; insurers; and government agencies.
3. *To improve quality while reducing cost of care* by increasing the appropriate use of drugs, biological products, and devices and by preventing their adverse effects and consequences of these effects (such as unnecessary hospitalizations).

Background

Since 1992, AHRQ has funded studies focused on patient outcomes associated with pharmaceutical therapy. Through this Pharmaceutical Outcomes Program, these studies have addressed many important questions regarding the management of drug prescribing.

The CERTs concept grew out of recognition that, while pharmaceuticals and other medical products improve the lives of many patients, underuse, overuse, adverse events, and medical errors may cause serious impairment to patient health. Of note is that the following gaps in knowledge remain:

- Limited comparative information exists on the risks, benefits, and interactions of both new and older agents; and
- Health professionals need guidance on the appropriate, cost-effective use of therapeutics that will, in turn,

lead to improved outcomes, error reduction, and prevention of adverse events.

CERTs Implementation

Because of AHRQ's demonstrated expertise in pharmaceutical outcomes research, it was given responsibility for administering the CERTs demonstration program authorized by Congress as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115). AHRQ awarded grants to support the first four centers in September 1999, and the full CERTs program was established as a permanent part of the Healthcare Research and Quality Act of 1999 (Public Law 106-129).

By September 2000, AHRQ had funded three additional centers, bringing the total to seven. Each center focuses on therapies used in a particular patient population or therapeutic area (see box). These seven centers, a Coordinating Center, a Steering Committee, and numerous partnerships with public and private organizations now make up the CERTs program.

CERTs Impact

The centers have completed several important projects since their inception. Researchers at the University of North Carolina center published a study[1] showing a link between rickets in breast-fed children and a lack of vitamin D supplementation, especially among black infants. As a result of this study, the North Carolina Department of Health and Human Services made vitamin D available free to breast-feeding women through its Women, Infants, and Children (WIC) program.

In another study, researchers at the Duke University center examined trends in aspirin use, patient characteristics, and long-term outcomes for aspirin effectiveness in more than 25,000 patients with cardiovascular diseases. They found that the percentage of patients with heart disease who report taking aspirin regularly increased between 1995-99.[2] These findings reflect substantial improvements in practice; but additional patients could benefit from this inexpensive, effective treatment that reduces death from heart disease, recurrent heart attacks, and stroke. The U.S. Preventive Services Task Force recommends that clinicians discuss the benefits and risks of aspirin therapy with adults who are at risk for coronary heart disease.

Another CERTs accomplishment is the Web-based International Registry for Drug-Induced Arrhythmias developed by the University of Arizona center (formerly located at Georgetown University). The information on clinical cases of drug-induced cardiac arrhythmias collected by the registry will be used to develop: 1) detailed profiles of people most at risk for these arrhythmias, and 2) a genetic test that can identify them in advance. The registry can be accessed online at www.qtdrugs.org.

The Arizona center, in collaboration with FDA's Center for Drug Evaluation

[1]Kreiter SR, Schwartz RP, Kirkman HN Jr, et al. Nutritional rickets in African American breast-fed infants. J Pediatr 2000 Aug; 137(2):153-7.

[2]Califf RM, DeLong ER, Ostbye T, et al. Underuse of aspirin in a referral population with documented coronary artery disease. Am J Cardiol 2002 Mar 15; 89(6):653-61.

Center	Emphasis
Duke University (HS10548) Principal investigator: Judith M. Kramer, M.D., M.S.	Therapies for disorders of the heart and blood vessels
HMO Research Network (HS10391) Principal investigator: Richard Platt, M.D., M.Sc.	Usefulness of HMOs for studying drug use, safety, and effectiveness
University of Alabama-Birmingham (HS10389) Principal investigator: Kenneth G. Saag, M.D., M.Sc.	Therapies for disorders of the joints and bones
University of Arizona (HS10385) Principal investigator: Raymond L. Woosley, M.D., Ph.D.	Reduction of drug interactions, especially in women
University of North Carolina (HS10397) Principal investigator: William H. Campbell, Ph.D.	Therapies for children
University of Pennsylvania (HS10399) Principal investigator: Brian L. Strom, M.D., M.P.H.	Therapies for infection, antibiotic drug resistance
Vanderbilt University (HS10384) Principal investigator: Wayne A. Ray, Ph.D.	Prescription drug use in a Medicaid population

and Research, has released its online clinical pharmacology educational module, "Preventable Adverse Drug Reactions: A Focus on Drug Interactions." The module was based on a needs survey sent to all third-year medicine clerkship directors and all medicine residency program directors in the United States. It consists of a set of slides illustrating a sample case, extensive literature references, and self-assessment questions. The module is available at: www.fda.gov/cder/drug/drugReactions/default.htm

Partnerships and Collaboration

A core value of the CERTs program is the belief that collaboration among groups with different perspectives and resources is critical if the results are applicable in "real world" settings. The centers work with public and private collaborators on projects, which allows each center to expand the number of its projects and extend their potential impact.

To collaborate with other organizations interested in advancing the best use of therapeutics, a "Partnerships to Advance Therapeutics" (PATHs) program was established as an integral part of the CERTs initiative.

The University of Alabama center recently collaborated with the Maryland Arthritis Foundation to develop a research program for the study of arthritis. The goal of this program is to expand knowledge through research in this field.

The CERTs Coordinating Center (see below) is currently organizing a series of workshops focusing on the risks of therapeutics. The CERTs program is hosting the workshops in collaboration with AHRQ, FDA, and the Pharmaceutical Research and Manufacturers of America (PhRMA). The goal of this series is to put forth a research agenda to improve the assessment, communication, and management of therapeutic risk.

CERTs Coordination

Duke University is the CERTs Coordinating Center. Directed by Robert M. Califf, M.D., the Coordinating Center helps support the work of the research centers by enhancing cross-center synergy and disseminating findings from the research conducted by the centers.

A Steering Committee, organized by the Coordinating Center, serves in an advisory capacity to the CERTs program. Steering Committee members include representatives from each center, the Federal Government (AHRQ, FDA, and currently the National Institutes of Health), the private sector, and consumer groups. In addition, work groups of representatives from all centers address broad issues related to the CERTs effort, such as public-private partnerships.

AHRQ's Center for Outcomes and Effectiveness Research oversees the CERTs program and provides technical assistance and research support.

For More Information

For more information on the CERTs program, visit the AHRQ Web site (www.ahrq.gov) or contact:

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www.ahrq.gov

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